REMARKS

Favorable reconsideration of the present application as currently constituted is respectfully requested.

Claims 1-7 and 9-13 are pending in the application. Claims 1, 7 and 13 are independent.

Claims 1-4, 6, 7, 11 and 12 have been amended for clarity with respect to the specification and drawings, and not in response to any statutory requirement.

New claims 8 and 14-43 have been added. Claims 17, 32 and 40 are independent claims.

No new matter is introduced.

Claim Rejections - 35 U.S.C. 102 - U.S. Patent No. 5,373,859

In the pending Office Action, claims 1-3, 5-7, 9-11 and 13 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,373,859 to Forney (hereinafter "Forney"). Applicant respectfully traverses these rejections for the reasons now following.

Applicant's amended claim 1 is directed towards one embodiment of the present invention, namely, a tongue retention device comprising a flange and a protrusion whereby the flange and protrusion comprise an integrally molded one-piece body. As stated at page 7, lines 25-26, of the present application, the protrusion (or bulb) "is unitarily formed with flange 14 thereby forming a one piece tongue retention device 10 as described in detail above" [emphasis added]. Further, Applicant states at page 7, lines 19-22, of the disclosure that such one-piece body can be formed by manufacturing procedures such as blow molding, injection molding, casting, vacuum forming and the like.

While the Forney reference teaches a tongue retention device comprising a flange and a tongue housing, in all embodiments the flange is formed separately from the housing and then later attached to the housing. Forney does not teach a flange and a protrusion (*i.e.* tongue housing) that comprise an integrally molded one-piece body. In the instant case the flange and protrusion do not have to be pressed fitted or glued together because these two components are in fact a single, one-piece body formed by a molding-like manufacturing procedure. Hence, the tongue retention device is manufactured from a single mold using a single material, hence, ensuring uniformity of material throughout the entire device.

There are definite commercial advantages in having a tongue retention device designed as a one-piece molded body. For example, such a device would likely be easier and cheaper to make than those tongue retention devices which have several elements that need to be manufactured separately and then "pieced" together. As well, the manufacturing time would likely be much less for a one-piece device. Finally, quality control would be much easier.

It is respectfully submitted that there is nothing in Forney to suggest that the flange and protrusion/housing comprise an integrally molded one-piece body. Rather, Forney teaches away from such an element. In particular, Forney states at paragraph 5, lines 16-17 that "[t]he flange 40 is preferably molded from a thin sheet of material" or, in the alternative, that "[t]he flange 40...is a simple collar 40 prime cut from a flat plate of rigid material". Clearly, Forney anticipates forming the flange separately from the rest of the tongue retention device.

The Examiner points out on page 3, paragraph 5, of his Detailed Action that "Applicant has not claimed any novel means of attaching the body together". However, it is respectfully submitted that claim 1 as now amended which recites an integrally molded one-piece body does in effect claim a novel means of forming the body (which includes a flange) of a tongue retention device.

As the Forney reference does not teach all of the elements of amended claim 1, it is respectfully submitted that claim 1 and dependent claims 2 to 6 (as amended) are not anticipated by this prior reference.

Applicant's amended claim 7 recites a tongue retention device comprising a flange and a tongue housing, *i.e.* bulb, wherein the bulb has an aperture for receiving the tongue and the proximal end of the aperture is contiguous with the flange. Thus, as can be seen most clearly in Figure 1 of the present application, the only element of the device that extends from the flange is bulb 18, which extends from the distal end of the aperture and the first surface of the flange. Hence, the proximal end of the device as a whole is the flange itself as the bulb only extends from the distal end of the aperture (and first surface of flange). Hence, no part of the tongue retention device of the present invention extends proximally from the flange. Thus, when the flange is properly positioned in a user's mouth between the user's lips and frontal surface of the user's teeth, there is no part of the device that extends into the user's oral cavity. The fact that the

present tongue retention device does not protrude into the oral cavity is one of the advantages of the present device over other devices (see, for example, page 10, lines 18-20).

In Forney, however, the flexible seal opening 30, which is disposed at the proximal end of the housing 10 and is comparable to Applicant's aperture, is not contiguous with the flange 40. In fact, housing 10 (and hence flexible seal opening 30) extends well beyond the proximal end of flange 40 such that the proximal end of flange 40 is not the most proximal element of the Forney device. This can most clearly be seen in Figure 5, where the proximal end of housing 10 clearly extends past the proximal end of flange 40. This structural difference can be seen in all embodiments of the Forney device, *i.e.* in Figures 1, 2, 3 and 6. Thus, the Forney device is structurally, and, consequently, functionally, very different than the present device as claimed in amended claim 7.

The resulting functional difference between the present device and Forney can be best described with reference to Figures 4 and 5 of Forney. It is clear from viewing Figures 4 and 5 (and also from reading the Forney specification) that the flange of the Forney device is intended to rest against the face of the subject, *i.e.* against the (outer) lips, and/or surrounding tissue (see Forney, column 5, lines 40-42). In particular, Figure 5 clearly shows flange 40 as being in front of the user's lips. In fact, as stated in column 5, lines 43-43, flange 40 may include a projection 42 that extends proximally and engages the chin and lower lip to help hold the flange 40 in place. Thus, because the flange rests on the user's face, in order to function the Forney device requires that the tongue housing 10 (*i.e.* the flexible seal opening 30) extend proximally from the flange in order that a vacuum can be maintained to ensure a sealing engagement of the user's tongue. If this proximal end were not present in the Forney device, when the device is positioned on the user's face, a proper suction could not be maintained. Hence, unlike the present device, the Forney device extends into the oral cavity of the user.

As the Forney reference does not teach all of the elements of amended claim 7, it is respectfully submitted that amended claim 7 and dependent claims 8 to 12 (as amended) are not anticipated by this prior reference.

Applicant has amended claim 13 to more clearly describe the present method of retaining a tongue in a predetermined position. In particular, the last step of said method now reads, "positioning said flange between a user's lips and frontal surface of said user's teeth". The

Examiner states that Forney discloses in figure 4 positioning of the tongue retention device between the user's lips and teeth. Arguably, parts of the Forney device may be viewed as being "positioned between" the user's lips and teeth, *i.e.* extending past a user's lips and teeth (see Figure 5). However, claim 13 has been amended to clearly recite that it is the flange that is positioned between the user's lips and frontal surface of the user's teeth. As can be clearly seen in both Figures 4 and 5 of Forney, and from reading the specification and, in particular, claim 22, the flange of the Forney device is positioned against a subject's face. Thus, Forney does not teach a method for retaining a tongue in a predetermined position which includes the step of positioning said flange between a user's lips and frontal surface of said user's teeth and hence does not anticipate claim 13.

Claim Rejections – 35 U.S.C. 103 - U.S. Patent No. 5,373,859 and U.S. Patent No. 5,465,734

In the pending Office Action, Claims 4 and 12 were rejected under 35 U.S.C. § 103(a) as being obvious in view of Forney and U.S. Patent No. 5,465,734 to Alvarez (hereinafter "Alvarez"). Applicant respectfully traverses these rejections for the reasons now following.

Claim 4 as amended is dependent on claim 1 and recites a tongue retention device comprising a flange and a protrusion whereby the flange and protrusion comprise an integrally molded one-piece body, wherein said integrally molded one-piece body is formed of a pliable material selected from the group consisting of polyethylene, urethane, silicon, and polyvinylchloride. Forney does not teach a device where the flange and protrusion comprise an integrally molded one-piece body. Thus, Forney does not "disclose in figures 1-5 a device for retaining a tongue, substantially as claimed". Neither does Forney suggest such an element. Thus, it would not be obvious to the skilled artisan to make a tongue retention device as claimed in claim 4 in view of Forney and Alvarez.

Claim 12 as amended is dependant upon claim 8, which in turn is dependant upon claim 7. Thus, claim 12 recites a tongue retention device comprising a flange having an aperture and a bulb wherein the proximal end of the aperture is contiguous with the flange. Further, the flange and bulb comprise an integrally molded one-piece body. Forney does not teach a device where the flange and bulb comprise an integrally molded one-piece body. Furthermore, Forney does

not teach a device where the aperture is contiguous with the flange. Thus, Forney does not "disclose in figures 1-5 a device for retaining a tongue, substantially as claimed". Neither are these elements suggested in Forney. Thus, it would not be obvious to the skilled artisan to make a tongue retention device as claimed in claim 12 in view of Forney and Alvarez.

Thus, it is respectfully submitted that the Examiner has failed to make a *prima facie* case of obviousness.

Favorable reconsideration of claims 1-7 and 9-13 is respectfully requested.

New Claims

There are other structural differences between the tongue retention device of the Forney reference and the present invention and these differences have been used as the basis for the new claims 17-43. Claims 17, 32 and 40 are independent claims.

New claims 8, 15 and 16 are all dependant on amended claim 7 and allowable for the reasons stated above. New claim 14 is dependant upon amended claim 13 and allowable for the reasons stated above.

With reference first to new claim 17, it is respectfully submitted that new independent claim 17 and new dependant claims 18-31 are allowable for the reasons now-following.

Independent claim 17 recites a tongue retention device comprising a bulb having a closed and open end and a flange that extends outwardly from the open end. This element is not found in Forney. In the Forney device, flange 40 does not extend outwardly from the open end of the housing 10, *i.e.* flexible seal opening 30. This can be clearly be seen in Figures 1, 2, 3, 5 and 6 of Forney.

As a result of the present invention having a flange which extends outwardly from the open end of the tongue housing (bulb), no element of the present device extends proximally from the flange. This is not the case with the Forney device (once again, refer to Forney Figures 1, 2, 3 and 6). Hence, when the flange of the present invention is properly positioned in a user's mouth between the user's lips and frontal surface of the user's teeth, no part of the present device extends into the user's oral cavity. As previously mentioned, the fact that the present tongue

retention device does not protrude into the oral cavity is listed as one of the advantages of the present device over other devices (see, for example, page 10, lines 18-20).

Hence, it is respectfully submitted that Forney does not teach a flange that extends outwardly from the open end of the tongue housing. Accordingly, based on the foregoing analysis, Applicant respectfully submits that claims 17-31 are also allowable over the cited prior art.

With consideration to claim 32, the Forney reference does not teach a flange which is sized and shaped to be comfortably received between a person's lips and frontal surface of a person's teeth or alveolar ridges if teeth are absent. Instead, the Forney flange 40 is sized and shaped to "rest against the face of the subject, *i.e.*, against the lips, teeth and/or surrounding tissue" (see column 5, lines40-42). Further, Forney states at column 5, lines 37-40 that "the flange is most preferably sized to extend from beneath the patient's nose to the chin area, thereby partially covering the mouth" [emphasis added]. Finally, the Forney flange 40 "most preferably includes a projection 42 that extends proximally and engages the chin and lower lip to hold the flange in place" (see column 5, lines 43-45).

In view of the above, it is clear that Forney does not teach nor even suggest a flange which is sized and shaped to be received between the lips and teeth. In fact, Forney teaches away from such a flange as it would likely be impossible to comfortably insert a flange as described at column 5, lines 37-40, between a person's lips and teeth. Hence, it is respectfully submitted that Forney does not teach a flange which is sized and shaped to be comfortably received between a person's lips and frontal surface of a person's teeth or alveolar ridges if teeth are absent. Accordingly, based on the forgoing analysis, Applicant respectfully submits that claim 32 and dependent claims 33 to 39 are also allowable over the cited prior art.

With consideration to claim 40, the Forney reference does not teach a flange which is constructed of a pliable material to be comfortably received between a person's lips and frontal surface of a person's teeth or alveolar ridges if teeth are absent. The flange 40 in Forney is a rigid member. It is either made rigid by cutting it from a flat plate of rigid material (see column 5, lines 49-51) or by providing it with a peripheral wall for strength (see column 5, lines 16-18). In fact, when the Forney tongue housing 10 is constructed of flexible material, it is "rendered

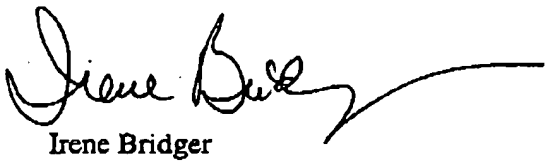
rigid by the incorporation of supporting members, one of which may be the flange 40" [emphasis added] (see column 3, lines 39-41).

Thus, it is clear from the above that the Forney flange is not pliable, either due to the material from which it is made or due to other structural elements attached thereto and thus is not intended to be inserted between a user's lips and teeth. Hence, it is respectfully submitted that Forney does not teach a flange which is constructed of a pliable material to be comfortably received between a person's lips and frontal surface of a person's teeth or alveolar ridges if teeth are absent. Accordingly, based on the forgoing analysis, Applicant respectfully submits that claim 40 and dependent claims 41 to 43 are also allowable over the cited prior art.

SUMMARY AND CONCLUSION

In view of the arguments presented by applicant herein, applicant submits that claims 1 to 43 are in a condition for allowance and such allowance is respectfully requested.

Respectfully submitted,



Irene Bridger
Registration No. 53,914

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Bennett Jones LLP
4500 Bankers Hall East
855 2nd Street SW
Calgary, Alberta T2P 4K7
(403) 298-3661